K073277

MAR - 6 2008

510(k) Summary – C-Reactive Protein (Latex)

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
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Indianapolis IN 46250
(317) 521-7637

Contact person: Kerwin Kaufman

Date prepared: November 21, 2007

Submission Purpose

Roche Diagnostics hereby submits this Special 510(k): Device Modification to provide notification of modifications to our C-Reactive Protein (Latex) assay. This assay was originally cleared for use in K981897 on the COBAS Integra 700 (analyzer cleared in K951595). Submission history for additional applications to the COBAS Integra family and to Roche/Hitachi cobas c systems are summarized in the following Submission History section.

Since the K981897 filing, several modifications to the C-Reactive Protein (Latex) application on the COBAS Integra platform include:

- change of calibrator and controls,
- validation of the high end of the measuring range of the assay up to 200 mg/L, and
- more specific Lipemia interference (L-Index) data provided based on testing with Intralipid instead of triglycerides.

The Limitations-interference section of the COBAS Integra labeling was also modified to include information about HAMA, monoclonal gammopathy, and additional testing of a common drug panel. This information is not a device modification but was provided for more safe and effective use of the assay.

A further device modification was validated in C-Reactive Protein (Latex) applications to the Roche/Hitachi cobas c 501 and cobas c 311:

- The high end of the measuring range was validated up to 250 mg/L

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Submission History

Applications of the K981897 CRP Latex modified reagent were applied to additional analyzers within the COBAS Integra family including Integra 400, 800, 400 Plus and cobas c 111, as well as Roche/Hitachi family cobas c 501 and c 311 analyzers via Letters to File *or* Internal Documentation per the Reagent Replacement policy:

- Integra 400, K951595/A003
- Integra 800, K951595/A008
- Integra 400 plus, K951595/A009
- cobas c 111, Internal Documentation, K981897/A003
- cobas c 501, Internal Documentation, K060373/A001 (referencing K981897)
- cobas c 311, Internal Documentation, K981897/A005

Device Name

Proprietary name: C-Reactive Protein (Latex)

Common name: C-Reactive Protein

Classification name: C-reactive protein immunological test system

Establishment Registration

The establishment registration number for Roche Diagnostics GmbH Penzberg is 9610126.

Classification

The FDA has classified the C-reactive protein immunological test system in Class II.

Panel	Classification Number	Classification Name	Regulation Citation
82 Immunology	DCN	C-reactive protein immunological test system	21 CFR 866.5270

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510(k) Summary – C-Reactive Protein (Latex), Continued

Device Description

The C-Reactive Protein (Latex) assay is a particle enhanced turbidimetric assay. Human CRP agglutinates with latex particle coated with monoclonal anti-CRP antibodies. The precipitate is determined turbidimetrically at 552 nm (546 nm on cobas c 501 and c 311 analyzers).

Intended use

In vitro test for the quantitative immunological determination of C-reactive protein in human serum and plasma on COBAS INTEGRA systems.

In vitro test for the quantitative determination of C-reactive protein in human serum and plasma on Roche/Hitachi **cobas c** systems.

Predicate Device

We claim substantial equivalence to the COBAS INTEGRA C-Reactive Protein (Latex) cleared as K981897.

Substantial equivalency – Similarities

The table below indicates the similarities between the modified C-Reactive Protein (Latex) test and its predicate device (original COBAS INTEGRA C-Reactive Protein (Latex), K981897).

Feature	Predicate: COBAS INTEGRA C-Reactive Protein (Latex) (K981897)	Modified device: C-Reactive Protein (Latex)
General		
Intended Use	The cassette COBAS INTEGRA C-Reactive Protein (Latex), (CRPLX) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA 700 for the quantitative immunological determination of human C-reactive protein in serum and plasma.	In vitro test for the quantitative immunological determination of C-reactive protein in human serum and plasma on COBAS INTEGRA systems. In vitro test for the quantitative determination of C-reactive protein in human serum and plasma on Roche/Hitachi **cobas c** systems.
Indications for Use	Measurements of C-reactive protein aids in evaluation of the amount of injury to body tissues.	Same

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510(k) Summary – C-Reactive Protein (Latex), Continued

Substantial equivalency – Similarities (continued)

Feature	Predicate: COBAS INTEGRA C-Reactive Protein (Latex) (K981897)	Modified device: C-Reactive Protein (Latex)
Specimen type	Serum and Plasma. Acceptable anticoagulants include heparin, EDTA, fluoride and citrate.	Same
Instrument platform	Integra 700 analyzer.	Integra family including Integra 700, 800, 400, 400 plus, and **cobas c**111. Also Roche/Hitachi family of **cobas** c systems including **cobas c**501 and **cobas c**311.
Test principle		
Determination of C-reactive protein	Particle enhanced turbidimetric assay. Human CRP agglutinates with latex particle coated with monoclonal anti-CRP antibodies. The precipitate is determined turbidimetrically at 552 nm.	Same Determined turbidimetrically at 546 nm on Roche/Hitachi **cobas** c systems
Reagent information		
Antibody	Mouse monoclonal anti-CRP antibodies	Same
Traceability	Traceable to the IFCC/BCR/CAP reference preparation CRM 470 (RPPHS 91/0619) for 14 serum proteins	Same
R1	TRIS buffer with bovine serum albumin and immunoglobulins (mouse) stabilized with 0.09% sodium azide (liquid)	Same
R2 = SR	Latex particles coated with anti-CRP (mouse) in glycine buffer stabilized with 0.09% sodium azide (liquid)	Same
Reagent stability	2-8 °C until expiration date On-board: 12 weeks	Same Note: On-board stability on **cobas** c 111, 5 weeks

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510(k) Summary – C-Reactive Protein (Latex), Continued

Substantial equivalency – Similarities (continued)

Feature	Predicate: COBAS INTEGRA C-Reactive Protein (Latex) (K981897)	Modified device: C-Reactive Protein (Latex)
Performance characteristics:		
Precision	Level 1, 6.2 mg/L CV within-run, 1.8% CV Total, 2.9% Level 2, 142 mg/L CV within-run, 1.5% CV Total, 2.7%	Same
Lower detection limit	0.25 mg/L	1.00 mg/L* * Performance has not changed. The *specification* is now stated as the claim
Method Comparison	COBAS Integra 700 CRP Latex (with CRP T Standard) versus COBAS Integra 700 with non-latex CRP (K951595): n=244 r=0.993 Lin. Regression, y = 1.07x – 6.2 mg/L P/B Regression, y = 1.00x – 2.7 mg/L Values ranged from 0.62 to 421 mg/L	COBAS Integra 700 CRP Latex (with CRP T Standard) versus COBAS Integra 700 CRP Latex (with Cfas Protein) n=150 r=0.999 Lin. Regression, y = 0.996x – 0.60 mg/L P/B Regression, y = 0.992x – 0.16 mg/L Values ranged from 0.62 to 362 mg/L

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510(k) Summary – C-Reactive Protein (Latex), Continued

Substantial equivalency – Differences

The table below indicates the differences between the modified C-Reactive Protein (Latex) test and its predicate device (original COBAS INTEGRA C-Reactive Protein (Latex), K981897).

Feature	Predicate: COBAS INTEGRA C-Reactive Protein (Latex) (K981897)	Modified device: C-Reactive Protein (Latex)
Calibrator	CRP T Standard (K954992)	Cfas Proteins (K012393)
Quality control	CRP T Control (K954992) CRP T Control N (K003400)	CRP T Control N Precinorm Protein (K012371) Precipath Protein (K012371)
Lipemia (L-index) Interference	Lipemia: Triglyceride levels higher than 7.5 g/L decrease the apparent CRP value significantly. Turbid samples exceeding 0.1 Absorbance are recognized by the "High Activity" check. Correct results can be obtained after post-dilution.	Lipemia: (Intralipid) **COBAS INTEGRA 400/400 plus analyzers:** No significant interference up to an L index of 1500 in the lower concentration range (3 mg/L or 28.6 nmol/L). No significant interference up to an L index of 623 in the higher concentration range (80 mg/L or 762 nmol/L). **COBAS INTEGRA 700/800 analyzers:** No significant interference up to an L index of 1094 in the lower concentration range (3 mg/L or 28.6 nmol/L). No significant interference up to an L index of 797 in the higher concentration range (80 mg/L or 762 nmol/L). There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration. Turbid samples exceeding 0.1 Absorbance are recognized by the "High Activity" check. Correct results can be obtained after postdilution.

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510(k) Summary – C-Reactive Protein (Latex), Continued

Substantial equivalency – Differences (continued)

Feature	Predicate: COBAS INTEGRA C-Reactive Protein (Latex) (K981897)	Modified device: C-Reactive Protein (Latex)
Measuring Range	0-160 mg/L 0-1600 mg/L with postdilution Postdilution factor of 10 recommended	Integra 700, 800, 400, 400 plus, and cobas c 111: 1-200 mg/L Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:10 dilution. Results from samples diluted by the rerun function are automatically multiplied by a factor of 10. **cobas** c 501 / c 311: 1-250 mg/L Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:3 dilution. Results from samples diluted by the rerun function are automatically multiplied by a factor of 3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Roche Diagnostics Corp.
c/o Mr. Kerwin L. Kaufman
Regulatory Affairs Principal
9115 Hague Rd.
Indianapolis, IN 46250

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Re: k073277
Trade/Device Name: Roche C-Reactive Protein (Latex)
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN
Dated: February 13, 2008
Received: February 19, 2008

Dear Mr. Kaufman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073277

Device Name: **Roche C-Reactive Protein (Latex)**

Indications For Use:

In vitro test for the quantitative immunological determination of C-reactive protein in human serum and plasma on COBAS INTEGRA systems.

In vitro test for the quantitative determination of C-reactive protein in human serum and plasma on Roche/Hitachi **cobas c** systems.

Measurements of C-reactive protein aids in evaluation of the amount of injury to body tissues.

Prescription Use XXX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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